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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,926

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,926	<b>Applicant(s)</b> CORL ET AL.	
	<b>Examiner</b> Karen E. Toth	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 56-69 is/are pending in the application.
- 4a) Of the above claim(s) 66 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29, 56-65, 68, 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/26/04, 1/9/04, 12/19/03</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of claims 25-29, 56-65, and 68-69 in the reply filed on 12 March 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 66-67 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 March 2007.

### ***Claim Objections***

3. Claim 27 is objected to because of the following informalities: Claim 27 refers to "the introducer"; since claim 25, from which claim 27 depends, does not disclose an introducer, it appears that claim 27 should depend from claim 26, which does disclose the system comprising an introducer. For examination purposes, the claim will be treated as such. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 25, 26, 28, 29, 63, and 64 are rejected under 35 U.S.C. 102(a) as being anticipated by Lebel (US Patent Application Publication 2003/0050547).

Regarding claim 25, Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains a gas sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). The examiner notes that, though an introducer is mentioned in the claim, it is not actually part of the claimed apparatus, and the probe of Lebel merely needs to be able to work with any device used as an introducer.

Regarding claim 26, Lebel further discloses using an introducer with the device (paragraphs [0058]-[0059]).

Regarding claims 28 and 29, Lebel further discloses the connector having a cylindrical portion (figure 1) and an electrical contact (paragraph [0031]), and the probe having a conductor extending from the electrical contact to the sensor

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and seated flush with the cylindrical portion (element 62; paragraphs [0042] and [0046]).

Regarding claims 63 and 64, Lebel discloses using gas-permeable material to form the cannula (element 66; paragraphs [0044], [0054]).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Schulman (US Patent 5497772).

Lebel discloses all the elements of the claimed invention, as described above, except for the introducer being a needle. Schulman teaches a system for implanting a blood component sensor comprising an introducer needle that is used to place a sensor probe (column 10, lines 10-24), in order to ease the

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insertion of the sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with an introducer needle, as taught by Schulman, in order to ease insertion of the sensor.

8. Claims 56-58 and 60-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Cheney, II (US Patent 5391250).

Regarding claim 56, Lebel discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors (elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

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Regarding claims 57 and 58, Lebel further discloses a sealed chamber in the cannula containing an electrolyte solution and the electrodes (paragraph [0054]-[0056]).

Regarding claim 60, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number of components and electrical connections in the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Cheney with the proximal end of the flex circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 61, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

9. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Schulman (US Patent Application Publication 2001/0051768).

Lebel in view of Cheney discloses all the elements of the claimed invention, as described above, except for the probe further comprising a second sealed chamber housing two additional electrodes and an electrolyte solution.

Schulman teaches an implantable probe for sensing components of blood comprising a plurality of sealed chambers (in this case, the combination of a "sensor assembly" and window), each having two electrodes (elements 12, 14, 16, 18) and an electrolyte solution (element 22) (paragraphs [0026]-[0027],

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0031], [0034-0037], [0062]), in order to allow sensing from a variety of areas within the patient's body without requiring multiple probes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Cheney with an additional chamber having electrodes and an electrolyte solution, as taught by Schulman, in order to allow sensing from a variety of areas within the patient's body without requiring multiple probes.

10. Claim 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Pantages (US Patent Application Publication 2001/0029337).

Lebel in view of Cheney discloses all the elements of the claimed invention, as described above, except for the probe comprising adhesive to hold the flex circuit in place in the cannula. Pantages teaches an implantable blood characteristic probe comprising a flex circuit held in place in a cannula using adhesive (paragraph [0084]), in order to ensure that the flex circuit does not move. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Cheney with adhesive securing the flex circuit within the cannula, as taught by Pantages, in order to ensure that it does not move.

11. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Kirsch (US Patent 6503225).



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Lebel discloses all the elements of the claimed invention, as described above, except for the gas permeable material being polymethylpentene. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material.

12. Claims 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Webber (US Patent 6166614).

Lebel discloses all the elements of the claimed invention, as described above, except for the system further comprising a display module with a connector for connecting to the probe's connector, allowing communication between the probe and display, and where the display module includes a band that makes it adaptable for securing to a patient's wrist.

Webber teaches an implantable probe system comprising a display module (element 22) that connects to and communicates with the implantable blood probe (elements 23, 24, 51), and comprises a band (element 28) that allows the display to be mounted on the patient's arm in a location of the user's choosing, such as the wrist (figure 1), in order to provide as much mobility to the patient as possible while still accurately monitoring the blood gas. It would have

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been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with a display module connected to the connector of the probe and secured to the patient's wrist, as taught by Webber, in order to provide mobility while monitoring blood gas.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5054882 to Riccitelli, which discloses a similar invention.

US Patent 5333609 to Bedingham, which discloses a similar invention.

US Patent 4573481 to Bullara, which discloses a similar invention.

US Patent 5655529 to Pontzer, which discloses a similar invention.

US Patent 4068659 to Moorehead, which discloses a similar invention.

US Patent 4474183 to Yano, which discloses a similar invention.

US Patent 4166469 to Littleford, which discloses a similar invention.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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